Dräger

510(k) Summary

DEC 2 0 2001

K010793

Summary of Safety and Effectiveness

Applicants Name and Address

Dräger Medical AG & Co. KGaA
Moislinger Allee 53-55
D-23542 Lübeck
Germany

Applicants Contact Person

Mr. Ulrich Schröder
Manager Regulatory Affairs

Tel. No.: (011 49) 451 – 882 3648
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Applicants US Contact Person

Mr James J. Brennan
Director Regulatory Affairs

Tel. No.: (215) 721-5400
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Date the Summary was prepared

November 19, 2001

Device Name

Trade Name:	**OXYLOG 1000**
Common Name:	Emergency and Transport Ventilator
Classification Name:	Ventilator, Continuous (per 21 CFR 868.5895)

Legally marketed device to which Substantial Equivalence is claimed

OXYLOG 2000 (K943531, K984577)
Manufactured by Dräger Medical AG & Co. KGaA, Germany

ParaPAC medic (K960515)
Distributed in the United States by SIMS PneuPAC USA

Description of the Device

The OXYLOG 1000 emergency and transport ventilator is a time-controlled, volume-constant emergency and transport ventilator offering the operating mode: controlled ventilation (CMV = Continuous Mandatory Ventilation). The rugged, gas powered device offers a simple and user friendly operating principle for optimum primary care.

The OXYLOG 1000 operates with a purely pneumatic system: The controls, monitoring as well as the alarms are realized by pneumatic components driven by the gas supply system.

The OXYLOG 1000 offers airway pressure limitation through all adjustable P_{max} settings. Once the pressure limit is reached the device sounds and displays an alarm and at the same time vents a partial flow to the atmosphere.

The OXYLOG 1000 is equipped with audible and visual alarms for: airway pressure low, (disconnection), airway pressure high (stenosis) and supply pressure low.

The OXYLOG 1000 is suited for mobile use in EMS and primary care of emergency patients, patient transports and transfers by land, sea and air, intra-hospital transfers of ventilated patients, secondary transfers between hospitals and in the emergency room.

Intended Use

The OXYLOG 1000 is a time cycled, constant volume, transport and emergency ventilator for patients requiring a minute volume ventilation of at least 3 liters per minute.

Substantial Equivalence

The intended use of the OXYLOG 1000 is covered by the referenced predicate devices. The materials and design are also similar to those predicate devices. The technical characteristics of the OXYLOG 1000 do not raise new questions regarding safety or effectiveness of emergency and transport ventilators. Furthermore, the labeling of the OXYLOG 1000 provides similar information as the predicate devices.

Information provided in the 510(k) submission supports the determination of substantial equivalence. Design, development and verification of the device was performed in accordance with FDA guidances and company internal standards. Performance testing was conducted using the IEC 60601 series of standards and other international and company internal standards. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

In summary Dräger Medical AG & Co. KGaA has demonstrated the OXYLOG 1000 to be safe and effective. The OXYLOG 1000 is considered to be substantial equivalent to currently marketed devices which have been previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Mr. James Brennan
Director Regulatory Affairs
Dräger Medizintechnik GmbH
C/o Dräger Medical, Inc.
3135 Quarry Road
Telford, PA 18969

Re: K010793
OXYLOG 1000
Regulation Number: 868.5895
Regulation Name: Powered Emergency Ventilator
Regulatory Class: Class II (two)
Product Code: CBK
Dated: July 19, 2001
Received: July 19, 2001

Dear Mr. Brennan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

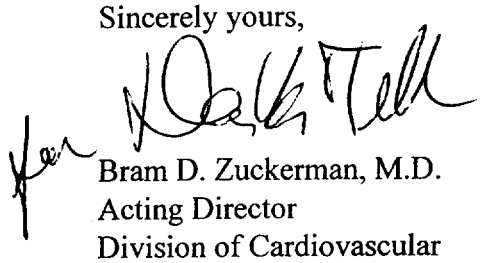
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010793

Device Name: OXYLOG 1000

Indications For Use:

The OXYLOG 1000 is a time cycled, constant volume, transport and emergency ventilator for patients requiring a minute volume ventilation of at least 3 liters per minute.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010793